

**Remarks**

This Amendment is responsive to the Office Action mailed February 27, 2007, which sets a three-month shortened statutory period for response, to end May 27, 2007. With this Amendment, Applicants cancel claims 4 and 7-12, and amend claims 1, 3, 6, and 16-19, and add new dependent claim 20, leaving claims 1-3, 6, and 16-20 pending and under consideration.

**Telephone Interview Summary**

On November 9, 2007, Applicants' representative, Sean Myers-Payne, conducted a telephone interview with Examiner Ungar. Applicants thank the Examiner for agreeing to an interview at this stage of prosecution and for the courtesies extended to Applicants' representative during the interview.

During the interview, Applicants' representative discussed with the Examiner the outstanding rejections in an attempt to better understand why the rejections were being made and what steps could be taken to overcome the rejections. No agreement was reached during the telephone interview.

**Claim Rejections – 35 U.S.C. § 112, First Paragraph**

The Office Action maintains the rejection of claims 1-4, 6-12, and 16-19, under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the enablement requirement. The rejection is maintained for the reasons previously presented. That is, the Action asserts that although the specification enables the use of "certain soluble ingredients from a microorganism as an adjuvant, [it] does not reasonably provide

enablement for the use of *any* soluble ingredient of a microorganism.” (Previous Office Action, mailed February 27, 2007.) In particular, the present Office Action emphasizes that the specification fails to explain how to distinguish between those extracts that will function as immunoadjuvants and those that will not. The Action again relies on Barot-Ciorbaru et al. for the argument that only certain soluble extracts possess immunomodulatory activity.

In response, Applicants first note that the claims have been amended to recite that the tissue or cell is one that has been “chemically fixed,” rather than “solidified.” Applicants respectfully note that formalin-fixation is exemplified throughout the specification, and that the reasons for its use are discussed in paragraph #3 toward the middle of page 3 of the specification. Applicants respectfully submit that formalin is simply one example of a class of chemical tissue fixatives, all of which result in crosslinking of biopolymers. Thus, Applicants respectfully submit that the exemplification of formalin and discussion of its action provide support for the recitation of “chemically fixed” in the claims.

Applicants further note that the claim have been amended to recite that the chemically fixed tissue or cell is “washed to remove components not crosslinked by chemical fixation.” Applicants respectfully submit that this amendment should address any concerns that the Examiner may have about which components are removed from, and remain in, the tissue or cell. Support for this amendment is found throughout the specification, and specifically, for example, by the last full paragraph of page 7 of the specification.

Finally, Applicants note that the claims have been amended to recite that “at least one soluble ingredient obtained from *Mycobacterium bovis* BCG is immobilized to the fragment.” Applicants respectfully submit that this amendment should address any concerns that the Examiner may have about which specific microorganism is to be used. Support for this amendment is found throughout the specification, and specifically, for example, in the Examples, beginning on page 19.

Notwithstanding the foregoing amendments and discussion, Applicants respectfully maintain that the previous claims were fully enabled by the specification. In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Claim Rejections – 35 U.S.C. § 103

The Office Action maintains the rejection of claims 1-4, 6-12, and 16-19 under 35 U.S.C. § 103 as allegedly unpatentable over Ohno et al. (CA 2362578) and Ravindernath et al. (U.S. Patent No. 6,218,166). The reasoning in the Office Action is the same as that set forth in the prior Office Action.

In response, Applicants initially respectfully submit that the arguments presented in response to the prior Office Action, particularly those explaining why Ohno and Ravindernath do not render obvious the present invention, are equally applicable to this rejection. Indeed, as the claims have been amended to even more particularly recite the claimed invention, those arguments are even more applicable in this Response.

Turning to the present amendments, Applicants respectfully note that the independent claims have been amended as discussed above. For example, the claims

have been amended to recite that the tissue or cell is one that has been "chemically fixed," rather than "solidified"; that the chemically fixed tissue or cell is "washed to remove components not crosslinked by chemical fixation"; and that "at least one soluble ingredient obtained from *Mycobacterium bovis* BCG is immobilized to the fragment." Applicants respectfully submit that at least this combination of elements of the claim are not suggested by the combination of Ohno and Ravindernath.


In view of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejection for obviousness.

#### Conclusion

In view of the foregoing remarks and amendments, Applicants respectfully submit that all pending claims are allowable over the art of record and in condition for allowance.

If the Examiner has any questions, or wishes to discuss further steps that may be taken to place the application in condition for allowance, the Examiner is requested to telephone the undersigned attorney.

Respectfully submitted,  
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